5748. Brites tablets. (F.D.C. No. 42199. S. No. 4–761 P.)

QUANTITY: 6 display cartons containing a total of 41 bottles at Virginia Beach, Va.

SHIPPED: 7–30–58, from Brooklyn, N.Y., by Commerce Drug Co., Inc.

LABEL IN PART: (Btl.) "25 Tablets BRITES Relieves Hangover * * * Active Ingredients: Salicylamide, Magnesium Hydroxi-amino-acetate, Caffeine, Kola, Mate, Frangula, and Calamus. Directions: * * * Caution: * * * Pektamol Laboratories, Inc., Brooklyn, N.Y. Distributors."

LIBELED: 9–19–58, E. Dist. Va.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for jittery feelings, upset stomach, dizziness, drowsiness, etc., associated with hangover, and would make one feel peppy; and 502(f)(2)—the labeling of the article failed to bear a statement warning that the article should be kept out of reach of children.

DISPOSITION: 10–27–58. Default—destruction.

5749. Rutone capsules and Rutone tablets. (F.D.C. No. 42205. S. No. 35–378 P.)

QUANTITY: 35 boxes at Dallas, Tex.

SHIPPED: From Philadelphia, Pa. This was a return shipment.

LABEL IN PART: (Box) "21 Capsules 42 Tablets * * * RUTONE TWO-WAY PLAN Relieves pain of Arthritis and Rheumatism Distributed by Preston Laboratories, Inc., Chicago, Illinois Each Capsule Contains: Thiamine Mononitrate (Vitamin B–1) 1.0 mg. Ascorbic Acid (Vitamin C) 20.0 mg. P.A.B.A. (Para-Amino-Benzoic Acid) 180 mg. Salicylamide 180 mg. Calcium Succinate 65 mg. Two enteric coated tablets supply: Sodium Salicylate 194 mg. Magnesium Salicylate 129 mg. Calcium Salicylate 129 mg. Each dose consists of two * * * tablets and One Capsule."

ACCOMPANYING LABELING: Leaflet in box entitled "The Rutone Two-Way Plan."

RESULTS OF INVESTIGATION: Analysis showed that the capsules contained less than the declared amount of para-aminobenzoic acid.

LIBELED: 10–8–58, N. Dist. Tex.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 180 milligrams of para-aminobenzoic acid per capsule; 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, rheumatic fever, osteoarthritis, fibrositis, and gout, and for the pain of such conditions, and that salicylamide, an ingredient of the capsules, was approximately seven times as effective in relieving pain as aspirin; and 502(f)(2)—the label of the article failed to bear a warning to keep it out of the reach of children, and a warning that if pain persisted for more than ten days, or redness was present, a physician should be called immediately.

DISPOSITION: 11–7–58. Default—destruction.

5750. Eileen Cortney multi-formula X21. (F.D.C. No. 41938. S. Nos. 30–494/5 P.)

QUANTITY: 220 8-oz. jars and 288 4-oz. jars at Sayville, N.Y.

SHIPPED: 2-1-58 and 7-11-58, from Chicago, Ill., by Solo Laboratories.

LABEL IN PART: (Jar) "Eileen Cortney Multi-Formula X21 * * * Beauty through the Ages. A balanced topical tissue nutritive compound in a rich base with medicinal quantities of Lecithin, Poly-unsaturates (Vitamin F) and G-11, a prophylatic. Eileen Cortney Inc.—New York Distr. Net Weight 8 oz." "Eileen Cortney Multi-Formula X21 Pentracin Net Weight 4 oz. * * * A topical tissue nutritive with medical values of STABILIZED Polyunsaturates (5%)."

ACCOMPANYING LABELING: Leaflets entitled "For a Healthier Skin" and "Eileen Cortney's Manual of Instructions."

RESULTS OF INVESTIGATION: The leaflets were prepared by Dewey Windale, president of Solo Laboratories, and printed at Sayville, N.Y. The term "G-11" appearing on the label of the 8-oz. jars is the registered trade name of hexachlorophene.

LIBELED: 7-24-58, E. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was a skin nutritive and an adequate and effective treatment for pre-aged, degenerated skin, psoriasis, all types of flabby, scaly, itching skin, wrinkles, infantile eczema, and atopic dermatitis; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in that the article was offered as a prophylactic, yet it failed to name the conditions for which its use would produce prophylaxis.

DISPOSITION. 8-26-58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

5751. **D.A.G. antiseptic.** (F.D.C. No. 41182. S. Nos. 24-018/9 M.)

INFORMATION FILED: 5-16-58, S. Dist. Calif., against Melchior T. Dikkers, Los Angeles, Calif.

SHIPPED: 1-27-56 and 6-25-56, from California to Arizona.

LABEL IN PART: (Btl.) "Net Contents 4 Ounces or ["One Pint"] D.A.G. Antiseptic * * * Manufactured by Dikkers Biochemical Laboratory, Los Angeles, California.

CHARGE: 501(c)—the strength of the article, when shipped, differed from, and its purity and quality fell below, that which it purported and was represented to possess, in that the article was represented as an antiseptic, whereas it was not an antiseptic but was contaminated with viable organisms. 502(a)—the statements in the labeling of the article, namely, "Antiseptic * * * for minor irritations, cuts, bruises, burns." were false and misleading since the article was not antiseptic, was contaminated with viable organisms, and was not adequate and effective in the treatment of minor irritations, cuts, bruises, and burns. The accompanying labeling of the article, namely, leaflets entitled "D.A.G. Dikkers Antiseptic and Germacide." and "D.A.G. a Theratropic Seaweed Extract with Tri-Iodophenols An Ethical Product for the Dental Profession." contained false and misleading representations

*See also Nos. 5744, 5749.